

Special 510(k) Premarket Notification
GE LOGIQ E9 Ultrasound System
July 24, 2008

1082185

Attachment B:

AUG 15 2008

Summary of Safety and Effectiveness *Prepared in accordance with 21 CFR Part 807.92(c).*



GE Healthcare

General Electric Company
P.O. Box 414, Milwaukee, WI 53201

Section a):

1. Submitter: GE Healthcare, Ultrasound and Primary Care Diagnostics, LLC
PO Box 414, Milwaukee, WI 53201
- Contact Person: Nicole Landreville, Eng. RAC
Leader, Diagnostic Ultrasound Regulatory Affairs
Telephone: 414-721-2272; Fax: 414-918-4498
- Date Prepared: July 29, 2008
2. Device Name: GE LOGIQ E9 Diagnostic Ultrasound System
Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO
Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN
3. Marketed Device: GE LOGIQBT08 Diagnostic Ultrasound System K073408.

4. Device Description: The LOGIQ E9 is a full featured, general purpose diagnostic ultrasound system which consists of a mobile console approximately 58 cm wide, 86 cm deep and 141 cm high that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls, 10-inch LCD touch screen and color 19-inch LCD image display. This modification will provide users with additional probe options, additional software options (V Nav and Scan Assistant) leading to overall quality and image enhancement. The LOGIQ E9 Diagnostic Ultrasound System is initially released with the following 13 probes: S1-5, C1-5-D, 3CRF, 9L-D, 11L-D, IC5-9-D, M4S-D, M6C-D, ML6-15-D, RAB2-5-D, RIC5-9-D, RNA5-9-D, RSP6-16-D.

5. Indications for Use: The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transrectal; Transvaginal; Transesophageal and Intraoperative (abdominal, thoracic, vascular and neurosurgical).

6. Comparison with Predicate Devices: The GE LOGIQ E9 is of a comparable type and substantially equivalent to the current GE LOGIQ BT08. It has the same technological characteristics, key safety and effectiveness features, and is similar in physical design, construction and materials and has the same intended uses and basic operating modes as the predicate device.

Section b):

1. Non-clinical Tests: The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical device safety standards.

Special 510(k) Premarket Notification
GE LOGIQ E9 Ultrasound System
July 24, 2008

2. Clinical Tests: None required.

3. Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms to 21 CFR 820, ISO 9001 and ISO 13485 quality management systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Healthcare that the GE LOGIQ E9 Diagnostic Ultrasound is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2008

Nicole Landreville, RAC
Leader, Diagnostic Ultrasound Regulatory Affairs
General Electric Company
GE Medical Systems, Ultrasound and Primary Care Diagnostics, LLC
9900 Innovation Drive
WAUWATOSA WI 53226

Re: K082185

Trade/Device Name: GE LOGIQ E9 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and IYN
Dated: July 29, 2008
Received: August 1, 2008

Dear Ms. Landreville:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the GE LOGIQ E9 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

S1-5
C1-5-D
3CRF
9L-D
11L-D

IC5-9-D
M4S-D
M6C-D
ML6-15-D
RAB2-5-D
RIC5-9-D
RNA5-9-D
RSP6-16-D

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

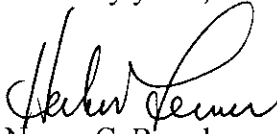
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

If you have any questions regarding the content of this letter, please contact Andrew Kang, M.D. at (240) 276-3666.

Sincerely yours,


for Nancy C. Brogdon

Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K082185

Device Name: GE LOGIQ E9 Diagnostic Ultrasound System

Indications For Use:

The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transrectal; Transvaginal; Transesophageal and Intraoperative (abdominal, thoracic, vascular and neurosurgical).

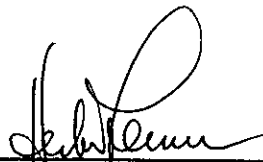
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

Prescription Use (Per 21 CFR 801.109)

510(k) Number

K082185

Diagnostic Ultrasound Indications for Use Form

K082185

GE LOGIQ E9 Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]	P	P	P	P	P	P	P	P	P	P	[5, 6]
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	[5, 6]
Pediatric	P	P	P	P	P	P	P	P	P	P	[5, 6]
Small Organ ^[2]	P	P	P	P	P	P	P	P	P	P	[5, 6]
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	[5]
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac ^[3]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[5, 6]
Musculo-skeletal Conventional	P	P	P	P	P	P	P	P	P	P	[5, 6]
Musculo-skeletal Superficial	P	P	P	P	P	P	P	P	P	P	[5, 6]
Other ^[4]	P	P	P	P	P	P	P	P	P	P	
Exam Type, Means of Access											
Transesophageal	P	P	P	P	P	P	P	P	P	P	
Transrectal	P	P	P	P	P	P	P	P	P	P	[5, 6]
Transvaginal	P	P	P	P	P	P	P	P	P	P	[5, 6]
Transurethral											
Intraoperative ^[8]	P	P	P	P	P	P	P	P	P	P	
Intraoperative Neurological	P	P	P	P	P	P	P	P	P	P	
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate.

[5] 3D/4D Imaging Mode.

[6] Includes imaging of guidance of biopsy (3D/4D).

[7] Includes infertility monitoring of follicle development.

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).

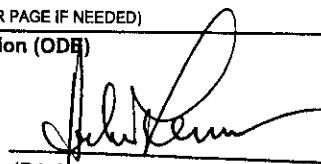
[9] Volume Navigation / Image Fusion / GPS /

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

System provides real-time 3D and 4D acquisition when used with special 4D probes.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K082185

Prescription Use (Per 21 CFR 801.109)

K082185

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ E9 with S1-5 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]	N	N	N	N	N	N	N	N	N	N	[6]
Abdominal ^[1]	N	N	N	N	N	N	N	N	N	N	[6]
Pediatric	N	N	N	N	N	N	N	N	N	N	[6]
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic	N	N	N	N	N	N	N	N	N	N	[6]
Cardiac ^[3]	N	N	N	N	N	N	N	N	N	N	[6]
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate.

[5] 3D/4D Imaging Mode.

[6] Includes imaging of guidance of biopsy (3D/4D).

[7] Includes infertility monitoring of follicle development.

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

System provides real-time 3D and 4D acquisition when used with special 4D probes.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K082185

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

K082185

GE LOGIQ E9 with C1-5-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]	N	N	N	N	N	N	N	N	N	N	[6]
Abdominal ^[1]	N	N	N	N	N	N	N	N	N	N	[6]
Pediatric	N	N	N	N	N	N	N	N	N	N	[6]
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	N	N	N	N	N	N	N	N	N	N	[6]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new Indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate.

[5] 3D/4D Imaging Mode.

[6] Includes imaging of guidance of biopsy (3D/4D).

[7] Includes infertility monitoring of follicle development.

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

System provides real-time 3D and 4D acquisition when used with special 4D probes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

K082185

GE LOGIQ E9 with 3CRF Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]											
Abdominal ^[1]	P	P	P		P	P	P	P	P	P	[5, 6]
Pediatric	P	P	P		P	P	P	P	P	P	[5, 6]
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	P	P	P		P	P	P	P	P	P	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate.

[5] 3D/4D Imaging Mode.

[6] Includes imaging of guidance of biopsy (3D/4D).

[7] Includes infertility monitoring of follicle development.

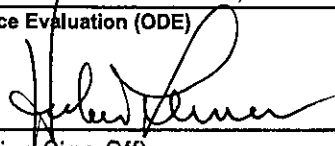
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

System provides real-time 3D and 4D acquisition when used with special 4D probes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K082185

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

K082185

GE LOGIQ E9 with 9L-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics ^[7]											
Abdominal ^[1]											
Pediatric	P	P	P		P	P	P	P	P	P	[5, 6]
Small Organ ^[2]	P	P	P		P	P	P	P	P	P	[6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[5, 6]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5, 6]
Musculo-skeletal Superficial											
Other ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new Indication; P = previously cleared by FDA; E = added under Appendix E

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic.
 - [2] Small organ includes breast, testes, thyroid.
 - [3] Cardiac is Adult and Pediatric.
 - [4] Other use includes Urology/Prostate.
 - [5] 3D/4D Imaging Mode.
 - [6] Includes imaging of guidance of biopsy (3D/4D).
 - [7] Includes infertility monitoring of follicle development.
 - [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
 - [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K082185

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

K082185

GE LOGIQ E9 with 11L-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]											
Abdominal ^[1]											
Pediatric	P	P	P		P	P	P	P	P	P	[5, 6]
Small Organ ^[2]	P	P	P		P	P	P	P	P	P	[5, 6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[5, 6]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5, 6]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[5, 6]
Other ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate.

[5] 3D/4D Imaging Mode.

[6] Includes imaging of guidance of biopsy (3D/4D).

[7] Includes infertility monitoring of follicle development.

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

System provides real-time 3D and 4D acquisition when used with special 4D probes.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

K082185

GE LOGIQ E9 with IC5-9-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]	P	P	P		P	P	P	P	P	P	[5, 6]
Abdominal ^[1]											
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal	P	P	P		P	P	P	P	P	P	[5, 6]
Transvaginal	P	P	P		P	P	P	P	P	P	[5, 6]
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate.

[5] 3D/4D Imaging Mode.

[6] Includes imaging of guidance of biopsy (3D/4D).

[7] Includes infertility monitoring of follicle development.

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

System provides real-time 3D and 4D acquisition when used with special 4D probes.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

Prescription User (Per 21 CFR 801.109)

K082189

Diagnostic Ultrasound Indications for Use Form

K082185

GE LOGIQ E9 with M4S-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]	P	P	P	P	P	P	P	P	P	P	[5, 6]
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	[5, 6]
Pediatric	P	P	P	P	P	P	P	P	P	P	[5, 6]
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac ^[3]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate.

[5] 3D/4D Imaging Mode.

[6] Includes imaging of guidance of biopsy (3D/4D).

[7] Includes infertility monitoring of follicle development.

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

System provides real-time 3D and 4D acquisition when used with special 4D probes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

K082/85

GE LOGIQ E9 with M6C-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]	P	P	P	P	P	P	P	P	P	P	[5, 6]
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	[5, 6]
Pediatric	P	P	P	P	P	P	P	P	P	P	[5, 6]
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic.
 - [2] Small organ includes breast, testes, thyroid.
 - [3] Cardiac is Adult and Pediatric.
 - [4] Other use includes Urology/Prostate.
 - [5] 3D/4D Imaging Mode.
 - [6] Includes imaging of guidance of biopsy (3D/4D).
 - [7] Includes infertility monitoring of follicle development.
 - [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
 - [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

K082185

GE LOGIQ E9 with ML6-15-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]											
Abdominal ^[1]											
Pediatric	P	P	P		P	P	P	P	P	P	[5, 6]
Small Organ ^[2]	P	P	P		P	P	P	P	P	P	[5, 6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[5, 6]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5, 6]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[5, 6]
Other ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic.
 - [2] Small organ includes breast, testes, thyroid.
 - [3] Cardiac is Adult and Pediatric.
 - [4] Other use includes Urology/Prostate.
 - [5] 3D/4D Imaging Mode.
 - [6] Includes imaging of guidance of biopsy (3D/4D).
 - [7] Includes infertility monitoring of follicle development.
 - [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
 - [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

Prescription User (Per 21 CFR 801.109)

K082185

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ E9 with RAB2-5-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]	P	P	P		P	P	P	P	P	P	[5, 6]
Abdominal ^[1]	P	P	P		P	P	P	P	P	P	[5, 6]
Pediatric	P	P	P		P	P	P	P	P	P	[5, 6]
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5, 6]
Musculo-skeletal Superficial											
Other ^[4]	P	P	P		P	P	P	P	P	P	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.

[2] Small organ Includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate.

[5] 3D/4D Imaging Mode.

[6] Includes imaging of guidance of biopsy (3D/4D).

[7] Includes infertility monitoring of follicle development.

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

System provides real-time 3D and 4D acquisition when used with special 4D probes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

K082185

GE LOGIQ E9 with RIC5-9-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]	P	P	P		P	P	P	P	P	P	[5,6]
Abdominal ^[1]											
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal	P	P	P		P	P	P	P	P	P	[5,6]
Transvaginal	P	P	P		P	P	P	P	P	P	[5,6]
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Notes:
- [1] Abdominal includes renal, GYN/Pelvic.
 - [2] Small organ includes breast, testes, thyroid.
 - [3] Cardiac is Adult and Pediatric.
 - [4] Other use includes Urology/Prostate.
 - [5] 3D/4D Imaging Mode.
 - [6] Includes imaging of guidance of biopsy (3D/4D).
 - [7] Includes infertility monitoring of follicle development.
 - [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
 - [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K082185

Prescription User (Per 21 CFR 801.109)

K082185

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ E9 with RNA5-9-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]	P	P	P	P	P	P	P	P	P	P	[5,6]
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	[5,6]
Pediatric	P	P	P	P	P	P	P	P	P	P	[5,6]
Small Organ ^[2]	P	P	P	P	P	P	P	P	P	P	[5,6]
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	[5]
Adult Cephalic											
Cardiac ^[3]	P	P	P	P	P	P	P	P	P	P	[5]
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[5,6]
Musculo-skeletal Conventional	P	P	P	P	P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial											
Other ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate.

[5] 3D/4D Imaging Mode.

[6] Includes imaging of guidance of biopsy (3D/4D).

[7] Includes infertility monitoring of follicle development.

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

System provides real-time 3D and 4D acquisition when used with special 4D probes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal and
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510(k) Number

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Diagnostic Ultrasound Indications for Use Form

K082185

GE LOGIQ E9 with RSP6-16-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[7]											
Abdominal ^[1]											
Pediatric	P	P	P		P	P	P	P	P	P	[5,6]
Small Organ ^[2]	P	P	P		P	P	P	P	P	P	[5,6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[5,6]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[5,6]
Other ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[8]	P	P	P		P	P	P	P	P	P	
Intraoperative Neurological	P	P	P		P	P	P	P	P	P	
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate.

[5] 3D/4D Imaging Mode.

[6] Includes imaging of guidance of biopsy (3D/4D).

[7] Includes infertility monitoring of follicle development.

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

System provides real-time 3D and 4D acquisition when used with special 4D probes.

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